CLAIMS

1. A monovalent influenza vaccine composition comprising an influenza virus component which is a low dose of egg-derived influenza virus antigen from an influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, in combination with a suitable adjuvant.

2. A vaccine composition according to claim 1 wherein the influenza virus antigen is in the form of purified whole influenza virus.

3. A vaccine composition according to claim 1 or claim 2 wherein the adjuvant is an aluminium salt or salts.

4. A vaccine composition according to claim 3 wherein the adjuvant is aluminium hydroxide and aluminium phosphate.

5. A vaccine composition according to claim 4 wherein the amount of aluminium phosphate exceeds the amount of aluminium hydroxide.

6. A vaccine composition according to any one of claims 3 to 5 wherein the aluminium salts are present in the range 0.4 to 1.0 mg per vaccine dose.

7. A vaccine composition according to any one of claims 1 to 6 wherein the low antigen dose is less than 15 µg of haemagglutinin per dose or no more than 15 µg per combined dose of vaccine.

8. A vaccine composition according to claim 7 in which the low antigen dose is less than 10 µg of haemagglutinin per dose or per combined dose of vaccine.

9. A vaccine composition according to claim 8 in which the antigen dose is between 0.1 and 7.5 µg, or between 1 and 5 µg of haemagglutinin per dose or per combined dose of vaccine.

10. A vaccine composition according to any one of claims 1 to 9 wherein the influenza virus antigen is substantially free of host cell contamination.

11. A vaccine composition according to any one of claims 1 to 10 wherein the influenza virus component is purified by a method which includes a protease incubation step to digest non-influenza virus proteins.

12. A kit comprising:

(i) a low dose of influenza virus antigen formulated with an adjuvant suitable for parenteral administration; and

(ii) a low dose of influenza virus antigen for mucosal administration, in a mucosal delivery device such as an intranasal spray device.

13. The kit according to claim 12, wherein the combined antigen dose of the parenteral and mucosal formulations is no more than 15 µg haemagglutinin.

14. The kit according to claim 13 wherein the combined antigen dose is less than 10 µg haemagglutinin.

15. The kit according to claim 13 or claim 14 wherein the influenza antigen in (i) is inactivated whole virus and the influenza antigen in (ii) is split virus.

16. The kit according to any one of claims 13 to 15 wherein the parenteral adjuvant is an aluminium salt or salts.

17. A method for the production of an influenza vaccine for a pandemic situation which method comprises admixing egg-derived influenza virus antigen from a single influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, with a suitable adjuvant and providing vaccine lots or vaccine kits which contain less than 10 µg influenza haemagglutinin antigen per dose or no more than 15 µg haemagglutinin per combined dose.

18. A method according to claim 17 wherein the antigen is highly purified.

19. A method according to claim 17 or claim 18 wherein the influenza virus antigen is in the form of whole influenza virus particles.

20. The vaccine composition or kit or method according to any one of claims 1 to 19 wherein the influenza antigen is selected from an H2 antigen such as H2N2 and an H5 antigen such as H5N1.

21. A process for producing influenza virus antigen for use in a vaccine, which process comprises the step of incubating a mixture containing influenza virus particles with a protease to digest non-influenza virus proteins.

22. A method according to claim 20 wherein the protease digestion step is performed after the influenza virus antigen has been partially purified by one or more physical separation steps.

23. A method according to claim 21 or claim 22 wherein the protease digestion step is performed prior to a virus inactivation step.

24. A method according to claim 23 wherein the purification process comprises the steps of:

(i) providing a harvested mixture of cultured influenza virus and host proteins from a culture;

(ii) partially purifying the influenza virus in the mixture by one or more physical purification steps;

(iii) performing a protease digestion step on the partially purified mixture to digest host proteins;

(iv) inactivating the influenza virus;

(iv) further purifying the influenza virus by at least one filtration step.

25. The use of below10 µg, or below 8 µg, or from 1 - 7.5 µg, or from 1 – 5 µg of egg-derived influenza virus haemagglutinin antigen from a single strain of influenza associated with a pandemic outbreak or having the potential to be associated with a

pandemic outbreak, in the manufacture of a vaccine lot or a vaccine kit for protection against influenza virus infection.

26. The use of no more than 15 μg, or below 10 μg, or below 8 μg, or from 1 - 7.5 μg, or from 1 – 5 μg of egg-derived influenza virus haemagglutinin antigen from a single strain of influenza associated with a pandemic outbreak or having the potential to be associated with a pandemic outbreak, in the manufacture of a two-dose vaccine for simultaneous parenteral and mucosal administration.

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